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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,040	06/29/2001	Mark E. Shannon	AEOMICA-011	7478

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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	5

DATE MAILED: 07/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/895,040	Applicant(s) SHANNON ET AL.	
	Examiner Jeanine A Goldberg	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 33-36, 45, 49-51, drawn to isolated nucleic acids, classified in class 536, subclass 23.1.

II. Claims 16-20, 37, 46, 49, 52-55, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 21, 38-42, 47-49, drawn to antibodies, classified in class 424, subclass 130.1.

IV. Claims 26-30, drawn to animals, classified in class 800, subclass 8.

V. Claims 22-23, drawn to a method of identifying binding partners for a polypeptide, classified in class 435, subclass 7.1.

VI. Claims 24, drawn to a method of modulating expression of a nucleic acid, classified in class 435, subclass 6.

VII. Claims 25, drawn to a method of modulating at least one activity of a polypeptide, classified in class 435, subclass 7.1.

VIII. Claims 31, drawn to a method of diagnosing a disease by detecting a mutation in the nucleic acid, classified in class 435, subclass 6.

IX. Claims 32, drawn to a method of diagnosing or monitoring a disease by measuring expression of a nucleic acid, classified in class 435, subclass 6.

X. Claims 32, drawn to method of diagnosing or monitoring a disease by measuring expression of a protein, classified in class 435, subclass 7.1.

XI Claims 43-44, drawn to a method of treating or preventing a disorder by administering polypeptide or antibody, classified in class 514, subclass 2.

XII. Claims 56, drawn to a method of screening for agents which modulate expression, classified in class 436, subclass 501.

2. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, II, III, and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The transgenic animal of Group IV is a composition made up of structurally and functionally complex biological systems. Furthermore, the products of Groups I, II, III, and IV can be used in materially different processes, for

example, the DNA of Group I can be used in hybridization assays, the antibody of Group III can be used in immunoassay, the polypeptide of Group II can be used to make fusion protein with an enzymatic function, while transgenic animals can be used to express different proteins other than SEQ ID NO: 3 (GRBP2). Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, III, and IV are patentably distinct from each other.

B) The inventions of Group V-XII are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group V is a method of identifying binding partners for a polypeptide. Group VI is a method of modulating expression of a nucleic acid. Group VII is a method of modulating at least one activity of a polypeptide. Group VIII is a method of diagnosing a disease by detecting a mutation in the nucleic acid. Group IX is a method of diagnosing or monitoring a disease by measuring expression of a nucleic acid. Group X is a method of diagnosing or monitoring a disease by measuring expression of a protein. Group XI is a method of treating or preventing a disorder by administering polypeptide or antibody. Group XII is a method of screening for agents which modulate expression. Groups V, VII, X, XI use proteins. Groups VI, VIII, IX, XI use nucleic acids. Moreover, each of the groups have different steps for their completion which are not overlapping with any other group. Therefore the methods are distinct over one another.

C) Groups (V, VII, X, XI) and Group I are patentable distinct inventions because the nucleic acid of Group I is not relied upon in the method of Groups V, VII, X, XI. Instead Groups V, VII, X, XI uses proteins. Therefore, the inventions are novel and unobvious over one another.

D) Groups VI, VIII, IX, XI and Group II are patentable distinct inventions because the proteins of Group II is not relied upon in the method of Groups VI, VIII, IX, XI. Instead Groups VI, VIII, IX, XI uses nucleic acids. Therefore, the inventions are novel and unobvious over one another.

E) Inventions VI, VIII, IX, XI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I may be used in numerous different nucleic acid screening assays including hybridization assays, mutation detection assays, aptamer assays, purification assays and the numerous assays as exemplified by the many assays claimed.

F) Inventions V, VII, X, XI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins may

be used for numerous additional assays as exemplified by the claimed inventions as well as generation of antibodies.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
July 29, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600